ARTICLE DETAILS

TITLE (PROVISIONAL)	Functional health literacy and glycemic control in older adults with type 2 diabetes: a cross-sectional study
AUTHORS	Souza, Jonas; Apolinario, Daniel; Magaldi, Regina; Busse, Alexandre; Campora, Flavia; Jacob-Filho, ; Wilson

VERSION 1 - REVIEW

REVIEWER	Fatima Al Sayah University of Alberta, Canada
REVIEW RETURNED	24-Oct-2013

GENERAL COMMENTS	This study addresses an important topic i.e. health literacy, and provides evidence on the relationship between health literacy and glycemic control in people with diabetes from a developing country, which is a very much needed research. The rationale and objectives of this study, and the methods were well explained; however, I have a few comments – mainly – regarding the analysis and interpretation of results. Major comments: • Abstract – conclusion: lines 43-44, the conclusion about the illiterate individuals is very minor since it was based on a very small sample, and thus should not be highlighted in the abstract. • Statistical analysis/Results: o In the logistic regression modes, the authors reported adjusted and unadjusted OR with 95%CI. The numbers within each group are too small to have stable estimates; this is evident in the reported 95%CI of all estimates (adjusted & unadjusted) that are too wide, which means that there is a lot of uncertainty around the OR. For example, the OR for the >=9% threshold for inadequate is ~ 9.2 with 95%CI 1.6, 53.8. In this case, it is better to only report results from multiple linear regression models, where health literacy and A1c are treated as continuous variables. o For multiple linear regression models, the results of adjusted and unadjusted models are almost the same (-0.1 vs -0.2) for health literacy. It is not clear why the authors adjusted for all of these variables given that most of them were non-significant in the bivariate analysis (i.e. unadjusted). It would also be more informative to run a model with only health literacy, then add socio-demographics, and then add the clinical variables, and report all coefficients, and R-squared of all models. Then, it might be useful to categorize health literacy into the three groups and examine associations with A1c (continuous); there might not be sufficient power to detect differences because the illiterate group is too small; however, the coefficients could be compared. o For all models, the authors did not mention anything about testing

for effect modification. Age, diabetes duration and depressive symptoms might modify the association between health literacy and glycemic control.
o Diabetes knowledge is known to be highly correlated with health literacy and it is best to leave out of the models.
o The authors did not adjust for the number or presence of comorbidities/complications in the models.
o Results: this section needs to be revised based on the revised analysis as suggested. If the authors decide to report the beta coefficients from the current analysis (adjusted & unadjusted), it is important to note that the magnitude of these coefficients is very small (0.1 & 0.2 in A1c), which is considered clinically unimportant. This has implications on how the authors interpret the findings and highlight their importance in the discussion section and the abstract. This is also why, the authors should be cautious about reporting the ORs from the logistic models.
o Discussion: needs to be revised after analysis is revised. For example, the authors mention "strong association observed in this study etc…"; the association (beta = 0.2) is actually weak. Additionally, the finding about the illiterate group is interesting; however, the authors also need to be cautious about over interpreting this result since it is based on a very small sample.

Minor comments:
• In the abstract, mention the number of the SAHLPA items
• In abstract, line 23, remove the word "extensive"
• In abstract, line 31, replace the "." After glycemic control to ";" so the reader knows that the adjusted OR reported in the next sentence refers to the previous sentence.
• In abstract, line 34, "poorer" than who?
• In abstract, lines 35-38, re-phrase "lower health literacy, lack of assistance of taking meds …. was associated with higher A1c" (A1c is the outcome).
• Page 5, line 21, correct the word glycolysated
• page 5, line 30, … change to "determine the independent association of health literacy with …."
• Page 6, lines 5-6, change to "eligibility criteria included"
• Page 8, line 45, of should be "or"
• Page 9, line 34, change "measure" to "examine" or explore
• Page 11, lines 34-35, what is "fifil" ? (I think that should be SD)
• Page 14, line 34, change "screened" to "screen"

REVIEWER	Jose Tique
	Friends in Global Health, Mozambique
REVIEW RETURNED	14-Nov-2013

| GENERAL COMMENTS | 4. As the authors very well mention in the introduction section, health literacy is not restricted to the ability of reading medical prescriptions and calculating dosages. It seems inaccurate and conceptually imprecise to refer to the Short Assessment of Health literacy for Portuguese Adults (SAHLPA) as a measure of health literacy when it only measures one component of it's construct (reading and comprehension). This is well pointed out in the discussion section, but It is important to be more specific throughout the paper when referring to the actual assessment that the instrument does. This also has implications to some of the conclusions made in the discussion section, where the association found between reading and comprehension (imprecisely described |

	as health literacy) and glycemic control is described. This should be revised.
	One of the inclusion criteria used in the study was the ability to speak Portuguese fluently. Can you elaborate more on how was this assessed? Was it self-reported? Was there an actual measure of Portuguese fluency applied?
	11. The authors did not find a relationship between the inability to read at all (described as illiteracy) and poor glycemic control as measured by their instrument and glycosylated hemoglobin. As this finding is inconsistent with a number of other studies, it might be useful to discuss possible reasons for the high levels of glycemic control found even among those unable to read. Are there structural factors (such as specific programs for low literacy patients, any specific monitoring program) that may reduce the effect on glycemic control?
	15. Despite being a very well written article, there are some grammatical errors found across the paper that need to be addressed.

VERSION 1 – AUTHOR RESPONSE

REVIEWER 1
Fatima Al Sayah
University of Alberta, Canada

MAJOR COMMENTS

COMMENT: Abstract – conclusion: lines 43-44, the conclusion about the illiterate individuals is very minor since it was based on a very small sample, and thus should not be highlighted in the abstract.
RESPONSE:
Thank you for pointing out this critical issue. We believe that the results concerning the subgroup of illiterate individuals are plausible and provide interesting insights. However, we agree that these results are preliminary and cannot be highlighted. Comments about the subgroup of illiterates were removed not only from the abstract's conclusion, but also from the title. These results are now presented on more conservative way.

COMMENT: In the logistic regression modes, the authors reported adjusted and unadjusted OR with 95%CI. The numbers within each group are too small to have stable estimates; this is evident in the reported 95%CI of all estimates (adjusted & unadjusted) that are too wide, which means that there is a lot of uncertainty around the OR. For example, the OR for the >=9% threshold for inadequate is ~ 9.2 with 95%CI 1.6, 53.8. In this case, it is better to only report results from multiple linear regression models, where health literacy and A1c are treated as continuous variables.
RESPONSE:
We have chosen to report results in the form of odds ratio (OR) with 95% confidence intervals (95%CI) manly because it is easy to understand. The readers are more familiar with interpreting the effect size of OR than a of beta coefficients. When judging the clinical relevance of the study findings, clinicians are likely to rely mostly on odds ratios.
An additional argument in favor of the OR (95% CI) approach is that the cutoffs which define inadequate health literacy and inadequate glycemic control were not chosen arbitrarily, but rather based on previous research. These criteria provide dichotomous classifications that have been shown to be scientifically valid and clinically meaningful.

Linear regression models may have certain limitations. They use HbA1c as a continuous variable and, thus, assume that a lower HbA1c is always better. But that may not always be the case. There is no convincing evidence that a patient with an HbA1c of 5.5% can be considered to have a better glycemic control than a patient with an HbA1c of 6.5%. Indeed, there is some evidence of potential harm in lowering HbA1c to less than 6.5% in older adults with type 2 diabetes (J Am Geriatr Soc 2013;61:2020-26).

Because both linear and logistic regression models have strengths and limitations, we believe that the reader would benefit from reports of both strategies. In response to the reviewer's concern regarding the large uncertainty around the OR (wide 95% CIs), we have made two major changes. First, linear regression models are now used in primary analyses and have been given a greater emphasis. Second, in the prior version of the article we investigated three alternative cutoffs for defining inadequate glycemic control (HbA1c > 7%, HbA1c > 8%, and HbA1c > 9%), but now we use only HbA1c > 8%, which is the threshold suggested by the American Geriatrics Society Expert Panel on the Care of Older Adults with Diabetes Mellitus (J Am Geriatr Soc 2013;61:2020-26). We believe that this threshold is more adequate than 7% for older adults and it provides a narrower 95% CI when compared with the 9% threshold.

COMMENT: For multiple linear regression models, the results of adjusted and unadjusted models are almost the same (-0.1 vs -0.2) for health literacy. It is not clear why the authors adjusted for all of these variables given that most of them were non-significant in the bivariate analysis (i.e. unadjusted). It would also be more informative to run a model with only health literacy, then add socio-demographics, and then add the clinical variables, and report all coefficients, and R-squared of all models. Then, it might be useful to categorize health literacy into the three groups and examine associations with A1c (continuous); there might not be sufficient power to detect differences because the illiterate group is too small; however, the coefficients could be compared.
RESPONSE:
Because we have a limited sample size, some variables may not be significantly associated in bivariate analysis, but still cause some bias that needs to be corrected. All the adjustment variables used in this study are theoretically relevant and have been shown in previous studies to be related with glycemic control and/or health literacy.
Our sample has heterogeneous socioeconomic backgrounds and there is not a single variable that could represent that diversity consistently. Thus we needed to use a variety of demographic variables. For example, in a preliminary analysis we had identified female gender as a risk factor for poor glycemic control. But when we include marital status into the model, gender is no more associated with glycemic control. In fact, widowhood is more frequent in women and has been shown to be associated with lack of social support and adverse health outcomes.
We are grateful to the reviewer for suggesting a hierarchical regression. A four-step model was implemented with reports of R2 and we believe that it greatly improved data presentation (Table 2).
A comparison of the HbA1c (as a continuous variable) between health literacy groups was conducted using the ANOVA test. The text has been amended to provide a more detailed description of the corresponding results. We believe that an ANCOVA analysis would be a third way to analyze the same data and thus would be unnecessary.

COMMENT: For all models, the authors did not mention anything about testing for effect modification. Age, diabetes duration and depressive symptoms might modify the association between health literacy and glycemic control.
RESPONSE:
Thank you for pointing out this critical issue. Although we had conducted interaction analyses, they had been omitted mainly because we did not find significant results.
In response to the reviewer's comment we now report the interaction analyses (pg 12 and 14).

COMMENT: Diabetes knowledge is known to be highly correlated with health literacy and it is best to

leave out of the models.
RESPONSE:
In our study the diabetes knowledge test was not highly correlated with the health literacy test (r=0.39), indicating that these two measures do not represent the same construct. In addition, the variance inflation factor of the SKILLD was only 1.70, indicating that it did not add significant multicollinearity to the regression model.

In a recent systematic review, Al Sayah et al. reported that "the association between health literacy and A1c was significant in studies that did not adjust for diabetes knowledge; however, that association was not observed in studies that controlled for diabetes knowledge" (J Gen Intern Med. 2013;28:444-52). Thus, we believe that this issue needs to be addressed.

We have now conducted a hierarchical regression including the SKILLD on the last step. With this new strategy the reader can examine the discrete incremental validity of the diabetes knowledge measure, as indicated by its beta coefficient and by the changes in the R2 (table 2).

COMMENT: The authors did not adjust for the number or presence of comorbidities/complications in the models.
RESPONSE:
Unfortunately, we don't have reliable information to calculate a comorbidity index. We only have data on diabetes complications, blood pressure and lipid profile. We believe that blood pressure and lipid profile are alternative health outcomes, but not predictors or mediators of glycemic control. We also believe that it would be improper to include diabetes complications as covariates in the regression models. We do not see diabetes complications as predictors, but as consequences of the glycemic control. Therefore, in this study, blood pressure and lipid profile are used only to describe the sample and diabetes complications are used only as outcomes (dependent variables).

COMMENT: Results: this section needs to be revised based on the revised analysis as suggested. If the authors decide to report the beta coefficients from the current analysis (adjusted & unadjusted), it is important to note that the magnitude of these coefficients is very small (0.1 & 0.2 in A1c), which is considered clinically unimportant. This has implications on how the authors interpret the findings and highlight their importance in the discussion section and the abstract. This is also why, the authors should be cautious about reporting the ORs from the logistic models.
RESPONSE:
We do not agree that the beta coefficients of the SAHLPA-18 are very small and clinically unimportant. We had reported regular (unstandardized) beta coefficients, which depend on the scaling of the measure and cannot have its effect size easily interpreted. For example, the unstandardized beta coefficient is 0.48 for gender and 0.19 for the SAHLPA-18, but gender is a dichotomous measure and the SAHLPA-18 is an 18-point measure. The corresponding standardized beta coefficients would be 0.16 for gender and 0.42 for the SAHLPA-18. In response to the reviewer critiques, we have decided to report standardized beta coefficients, which allow interpretation of effect sizes and comparisons between variables.

We have three main arguments to refute the statement that magnitude of the association is very small and clinically unimportant: (1) the variable more strongly associated with glycemic control in the final model is health literacy, with a standardized beta that is about two times greater than any other variable; (2) Cohen's d effect size for HbA1c between patients with adequate and inadequate health literacy is 0.44, which is considered to be moderate; (3) adjusted OR for poor glycemic control was 4.76 in patients with inadequate health literacy, which is considered to represent a large effect size by most authors.

In response to the reviewer's comments, we have made amendments to provide more objective information on the magnitude of the association between health literacy and glycemic control while avoiding subjective judgments.

COMMENT: Discussion: needs to be revised after analysis is revised. For example, the authors mention "strong association observed in this study etc…"; the association (beta = 0.2) is actually weak. Additionally, the finding about the illiterate group is interesting; however, the authors also need to be cautious about over interpreting this result since it is based on a very small sample.
RESPONSE:
We have now suppressed subjective interpretations about the magnitude of the associations, avoiding terms such as "strong association" in favor of terms such as "significant association". The issue regarding the subgroup of illiterate patients was already addressed on the preceding topics.

MINOR COMMENTS
- In the abstract, mention the number of the SAHLPA items
- In abstract, line 23, remove the word "extensive"
- In abstract, line 31, replace the "." After glycemic control to ";" so the reader knows that the adjusted OR reported in the next sentence refers to the previous sentence.
- In abstract, line 34, "poorer" than who?
- In abstract, lines 35-38, re-phrase "lower health literacy, lack of assistance of taking meds …. was associated with higher A1c" (A1c is the outcome).
- Page 5, line 21, correct the word glycolysated
- page 5, line 30, … change to "determine the independent association of health literacy with …."
- Page 6, lines 5-6, change to "eligibility criteria included"
- Page 8, line 45, of should be "or"
- Page 9, line 34, change "measure" to "examine" or explore
- Page 11, lines 34-35, what is "fifil" ? (I think that should be SD)
- Page 14, line 34, change "screened" to "screen"
RESPONSE:
We are greatly indebted to the reviewer for her careful review and for pointing out these minor issues. All the errors were corrected and most of the suggestions were implemented.

REVIEWER 2
Jose Tique
Friends in Global Health, Mozambique

COMMENT: As the authors very well mention in the introduction section, health literacy is not restricted to the ability of reading medical prescriptions and calculating dosages. It seems inaccurate and conceptually imprecise to refer to the Short Assessment of Health literacy for Portuguese Adults (SAHLPA) as a measure of health literacy when it only measures one component of it's construct (reading and comprehension). This is well pointed out in the discussion section, but It is important to be more specific throughout the paper when referring to the actual assessment that the instrument does. This also has implications to some of the conclusions made in the discussion section, where the association found between reading and comprehension (imprecisely described as health literacy) and glycemic control is described. This should be revised.
RESPONSE:
We agree that the SAHLPA only measures one component of the health literacy construct, i.e., comprehension of health-related written materials. This type of health literacy has been called "basic" or "functional health literacy" (Nutbeam D. Health Promot Int 2000;15:259-67). This somewhat narrow approach warrants practical feasibility for studies investigating the relationships between health literacy and health outcomes.
To make this point clear, we have now defined "functional health literacy" on the introduction section (pg 4) and replaced the term "health literacy" with "functional health literacy" throughout the paper.

COMMENT: One of the inclusion criteria used in the study was the ability to speak Portuguese

fluently. Can you elaborate more on how was this assessed? Was it self-reported? Was there an actual measure of Portuguese fluency applied?
RESPONSE:
We did not use a standardized measure to assess Portuguese fluency. It was self-reported. In Brazil Portuguese is the only official language. It is spoken by virtually the entire population. Thus, individuals who do not speak Portuguese are basically those who have recently emigrated from another country and they can be easily identified. We have now clarified this point (pg 6).

COMMENT: The authors did not find a relationship between the inability to read at all (described as illiteracy) and poor glycemic control as measured by their instrument and glycosylated hemoglobin. As this finding is inconsistent with a number of other studies, it might be useful to discuss possible reasons for the high levels of glycemic control found even among those unable to read. Are there structural factors (such as specific programs for low literacy patients, any specific monitoring program) that may reduce the effect on glycemic control?
RESPONSE:
We don't agree that this finding is inconsistent with a number of other studies. Actually, we don't know of any study that has demonstrated poorer glycemic control in illiterate patients when compared to patients with adequate health literacy or even when simply compared to literate patients. We have included a new paragraph and two references to improve the discussion of that issue (pg 17 and 18).

COMMENT: Despite being a very well written article, there are some grammatical errors found across the paper that need to be addressed.
RESPONSE:
Thank you. Spelling and grammatical errors were corrected. The text has been reviewed and is (hopefully) improved.

VERSION 2 – REVIEW

REVIEWER	Fatima Al Sayah University of Alberta, Canada
REVIEW RETURNED	06-Jan-2014

GENERAL COMMENTS	**Major comments:**
	o Abstract lines 30 – 32: Since the authors choose multiple linear regression to be the primary analysis, a beta coef with p-value should be reported in the abstract instead of OR. o Article summary – article focus: first point is not clear as authors mention self-care then glycemic control; would suggest rewriting this statement. In the second point, "at the very low end of the health literacy spectrum" needs to be clarified. Does it mean those who are illiterate? Or those with very low scores on health literacy measure? Also clarify this statement on page 5, line 43. o Page 11, lines 18 – 20: It is not clear what "between all significant variables" means in this sentence? o Page 12, lines 36 – 41: What are "post hoc tests"?

- Analysis:
  Standardized coefficients are usually reported when the objective is to examine which of the independent variables have a greater effect on the dependent variable in a multiple regression analysis. Since this is not the objective of this study, it is better to report unstandardized beta coefficients, which are easier to interpret. Again, although the beta coefficients were statistically significant, the authors need to be cautious about over interpreting these results (an adjusted difference of -0.2 in A1c with a unit increase in the HL measure is well below the minimal clinically important difference in A1c i.e. 0.5). These mild-moderate effects are the main concern regarding the results of the logistic regression models (an OR of 4.8).

  Re Logistic regression analysis: To clarify my previous comment regarding this analysis, I do not have a concern regarding using health literacy as a categorical variable; however, it was about using A1c (outcome) as a categorical variable.

- Page 13, lines 12 – 19: The findings regarding the linearity of the relationship between health literacy and glycemic control contradicts the finding regarding glyecmic control in illiterates (lowest health literacy group), as per this, the relationship between A1c and health literacy is curved. Would suggest reconsidering these conclusions.

- Page 15, 2nd paragraph: The discussion around the validity of the SKILLD warrants further revision. The correlation between literacy status and SKILLD in the original study by Rothman et al 2005 was 0.33, which is very similar to the finding in this study. The SKILLD was developed to assess diabetes knowledge in individuals with low health literacy, and thus a "high" correlation with a health literacy measure is not necessarily expected.

Minor comments:

- Abstract line 8: Remove the word "heterogenous"; the sample is small and ~ 70% were females, so it's not very heterogenous. Also suggest removing this word throughout the manuscript.

	o Abstract lines 45 – 47: Since this study was not about identifying (or screening) for inadequate HL in clinical settings, it's better to change the word "identifying" in the second statement of conclusion to "addressing".
	o Page 6, line 7: change "convenience" to "convenient"
	o Page 14, lines 45 – 49: In referring to the systematic review by Al Sayah et al, I suggest removing the word "only" as this suggestion was based on observing a trend where "most" of the studies that reported significant results were ones that did not adjust for diabetes knowledge.
	o Page 15, line 30: change "consistence" to "consistency"
	o Although the manuscript was well written, it could benefit from additional grammatical editing.

VERSION 2 – AUTHOR RESPONSE

REVIEWER 1
Fatima Al Sayah
University of Alberta, Canada

MAJOR COMMENTS

COMMENT: Abstract lines 30-32: Since the authors choose multiple linear regression to be the primary analysis, a beta coef with p-value should be reported in the abstract instead of OR.
RESPONSE:
The reviewer may have missed something. A beta coefficient with p-value for the health literacy (β=-0.42; $p<0.001$) is already reported in the abstract (lines 33-34).

COMMENT: Article summary – article focus: first point is not clear as authors mention self-care then glycemic control; would suggest rewriting this statement.
RESPONSE:
Thank you for pointing out this issue. We have now substituted "diabetes outcomes" for "diabetes self-care". We believe that the sentence is now clearer: "Although many theoretical mechanisms are proposed that link health literacy to diabetes outcomes, the direct association between functional health literacy and glycemic control is still controversial."

COMMENT: Article summary – article focus: in the second point, "at the very low end of the health literacy spectrum" needs to be clarified. Does it mean those who are illiterate? Or those with very low scores on health literacy measure? Also clarify this statement on page 5, line 43.
RESPONSE:
With "at the very low end of the health literacy spectrum" we meant both those who are illiterate and those with very low scores on the health literacy measure. This statement has been rewritten and is hopefully improved: "there is paucity of data on the adequacy of glycemic control in patients who are illiterate and in those who have only the most rudimentary levels of literacy." The statement on page

5, line 43, has been amended accordingly.

COMMENT: Page 11, lines 18-20: It is not clear what "between all significant variables" means in this sentence?
RESPONSE:
This sentence has been rewritten and we hope that it is now clearer: "In addition, we have investigated interactions between all the variables that were significantly associated with glycemic control in the fully adjusted linear regression model."

COMMENT: Page 12, lines 36 – 41: What are "post hoc tests"
RESPONSE:
Because the ANOVA detected a significant difference in HbA1c across health literacy levels, we must conduct a post hoc test for comparing each of the groups with each of the other groups. As a series of multiple t tests would inflate the probability of Type I error, a post hoc test was used to permit multiple comparisons and still maintain alpha at .05.
Post hoc tests used in this study are described in the Statistical Analysis section: "Post hoc tests for determining differences between means were accomplished with the Tukey's honestly significant difference procedure."

COMMENT: Standardized coefficients are usually reported when the objective is to examine which of the independent variables have a greater effect on the dependent variable in a multiple regression analysis. Since this is not the objective of this study, it is better to report unstandardized beta coefficients, which are easier to interpret.
RESPONSE:
There is a significant controversy over the choice between standardized or unstandardized beta coefficients. We agree with Andy Field when he states that "the standardized versions of the b-values are probably easier to interpret because they are not dependent on the units of measurement of the variables" (Discovering Statistics using IBM SPSS Statistics, Andy Field, SAGE, 2013).
We prefer standardized beta coefficients because we believe that they easy to interpret and allow the reader to compare the relative contribution of each independent variable in the prediction of the glycemic control. Thus, although we understand and respect the reviewer's opinion, we decided to report beta coefficients in the standardized form.

COMMENT: Again, although the beta coefficients were statistically significant, the authors need to be cautious about over interpreting these results (an adjusted difference of -0.2 in A1c with a unit increase in the HL measure is well below the minimal clinically important difference in A1c i.e. 0.5). These mild-moderate effects are the main concern regarding the results of the logistic regression models (an OR of 4.8).
RESPONSE:
There are important controversies surrounding judgments about effect sizes and we what should be considered "clinically important". We have provided to the reader objective information on the magnitude of the associations while avoiding subjective judgments.

COMMENT: Page 13, lines 12 – 19: The findings regarding the linearity of the relationship between health literacy and glycemic control contradicts the finding regarding glycemic control in illiterates (lowest health literacy group), as per this, the relationship between A1c and health literacy is curved. Would suggest reconsidering these conclusions.
RESPONSE:
The relationship between the SAHLPA-18 and HbA1c has been shown to be linear in our study. But in fact, illiterate individuals were not included in that analysis, as we do not have valid SAHLPA-18 scores for illiterate individuals.
Because this is not a major issue in our study, because this is a controversial point, and because a

short discussion might cause some misunderstandings, we decided to eliminate considerations regarding the linearity of the relationship between health literacy and glycemic control. Corresponding paragraphs were deleted.

COMMENT: The discussion around the validity of the SKILLD warrants further revision. The correlation between literacy status and SKILLD in the original study by Rothman et al 2005 was 0.33, which is very similar to the finding in this study. The SKILLD was developed to assess diabetes knowledge in individuals with low health literacy, and thus a "high" correlation with a health literacy measure is not necessarily expected.

RESPONSE:

We agree that a high correlation between a diabetes knowledge test and a functional health literacy test is no necessarily expected. Accordingly, we have eliminated the word "only" on the following sentence: "…the diabetes knowledge test was (only) moderately correlated with the measure of functional health literacy (r=0.39)"

Thank you for bringing this issue to our attention. We have noticed an error in that passage that may have caused confusion. The correct sentence is: "When the SKILLD was added to a model already containing the SAHLPA-18, demographic characteristics, and clinical factors, it was not significantly associated with glycemic control" (not functional health literacy). This error has been corrected.

MINOR COMMENTS

o Abstract line 8: Remove the word "heterogenous"; the sample is small and ~ 70% were females, so it's not very heterogenous. Also suggest removing this word throughout the manuscript.

o Abstract lines 45 – 47: Since this study was not about identifying (or screening) for inadequate HL in clinical settings, it's better to change the word "identifying" in the second statement of conclusion to "addressing".

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o Page 15, line 30: change "consistence" to "consistency"

o Although the manuscript was well written, it could benefit from additional grammatical editing.

RESPONSE:

We are greatly indebted to the reviewer for her careful review and for pointing out these minor issues. All these minor suggestions were implemented. Spelling and grammatical errors were corrected. The text has been reviewed and is (hopefully) improved.